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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,855	03/24/2004	Gary David Greenblatt	A01514	6658

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,855	GREENBLATT ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/04; 9/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 9/30/2004 and 11/15/2004. Claims 1-8 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutically active compounds, agricultural compounds and biocides, does not reasonably provide enablement for all active ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient number of the factors are discussed below for a *prima facie* case.

A. The Nature of the Invention:

The invention is drawn to extended release dosage form comprising polymer-clay platelets and an "active ingredient" and the release of the active ingredient.

B. State of the prior art:

Active ingredient is a broad designation of any agent that is active in any form such as surfactants, preservatives and chelating agents. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific guidance is required to enable the artisan to practice the full scope of the claimed invention. The scope of active ingredient is broader that the disclosed pharmaceutically active compounds, agricultural compounds and biocides and spans compounds and molecules that are not disclosed.

C. The amount or direction or guidance presented:

Guidance is provided for insecticide, ibuprofen and nicotine

Therefore, in view of the lack of guidance, working examples, breadth of the claims and state of the art at the time the claimed invention was made, it would have required undue experimentation to use the invention as claimed. It is noted that the specification must teach

those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). The courts have stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application. 27 USPQ2d 1662 *Ex parte Maizel.* Scope of Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

The above rejection may overcome by specifically reciting using Markush type language, the active ingredients contemplated for use in the claimed composition.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruskin (US 6,821,928 B2).

Ruskin discloses slow release product (abstract; column 2, lines 29-67; column 3, lines 13-22; column 5, lines 1-15) that comprises polymer-clay nano composite, in which the clay is 40% (abstract; column 8, line 22) meeting the requirement of claims 2, 4, 6 and 8. The polymer-clay composite is contemplated for delivery of herbicide and pesticide (claims 1-8) meeting claims 1, 3, 5 and 7.

5. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Beall et al. (US 6,461,423).

Beall discloses polymer-clay nano-composite comprising clay and polymer (column 5, lines 12-32; column 7, lines 12-28; column 8, lines 62-67; column 9, lines 5-26) for delivery of active compounds such as oxidizing agents, hair weaving lotions and drugs (column 7, lines 1-11); the product and the disclosure for delivery active compounds meets the limitations of claim 1, 3, 5 and 7. The polymer based on the dry weight of smectite clay is from about 50% to 80%, which means that the clay is at 50% to 20%.

6. Claims 1-8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Beall et al. (US 6,461,423).

Beall is described above as anticipating claims 1, 3, 5 and 7. The % clay based on the dry weight of the polymer-clay composite is from about 20% to about 50%. The %range recited in claim 2, 4, 6 and 8 is from 10% to 40%. Beall's range encompasses the recited range of 10% to 40% such that the % clay in Beall anticipates the recited range as in claim 2, 4, 6 ands 8. However, in the alternative, there are points within the disclosed % range for the clay in the composite of Beall, which include points within the recited range so that it would be prima facie obvious to use any % amount of clay within the disclosed range in the composite of Beall that would provide a composite for delivery of the active compounds. In the absence of factual evidence, the recited range of from 10% to 40% is not inventive over the range of from about 20% to about 50% taught by Beall.

7. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstl et al. ("Controlled Release of Pesticides into Water from Clay-Polymer formulations," in J. Agric. Food Chem. 1998, 46, 3803-3809) or Beall et al. (US 5,955,094) or Lan et al. (US 6,057,396).

Gerstl describes a composite of polymer and clay for the delivery of pesticides (abstract; pages 3804-3806). From a ratio of 3:4:2 for the polymer:clay:pesticide (experimental procedures on page 3804) mixed before the addition of water may provide about 57% of the clay based on the dry weight of the polymer-clay.

Beall polymer-clay composite (abstract; column 1, line 44 to column 2 line 44) for delivery of pesticides (column 3, lines 2-60; column 4, lines 11-20, 45-62; column 5, lines 3-38); the pesticide is preset at 40% (column 5, lines 56 and 57); the amount of polymer varies from 8 gram/100 gram polymer-clay; preferably 10 gram/100 gram polymer-clay to about 80-90 gram/100 gram polymer-clay; more preferred is from about 20 gram/100 gram polymer-clay to about 60 gram/100 gram polymer-clay, all the basis of dry weight (column 12, lines 32-44). The more preferred %amount of the polymer translates into %amount of clay from about 40% to 80%. The lower limit of Beall for the clay touches the upper limit recited in claims 2, 4, 6 and 8.

Lan discloses polymer-clay nano composites (title and abstract; column 6, lines 33-38; column 9, lines 15-30; column 28, lines 62-67) for the delivery of active compounds (column 9, lines 2-30; column 26, line 24 to column 27 line 25).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beall et al. (US 5,955,094).

Beall is discussed above to anticipate claims 1, 3, 5 and 7. Claims 2, 4, 6 and 8 recite clay in %amount of from 10-40% by weight of the dry polymer clay nano composite. Beall discloses a range of from about 40% to 80% because the most preferred amount of the polymer in the composite is from 20 to 60% derived from the contemplated preferred polymer in amount of 40% to 80% (column 12, lines 32-44). The lower limit of Beall at 40% for the clay touches the upper limit recited in claims 2, 4, 6 and 8. It would be prima facie obvious to use the 40% of the clay with the 60% of the polymer in the polymer clay composite that is based on the dry weight of the polymer-clay composite and expect the composite of Beall to be effective in the delivery of active compounds. The recited range of 10-40 wt% based on the dry weight of the polymer-clay composite is not inventive over the 40% of Beall in the absence of factual evidence.

11. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang et al. ("Thermosensitive Poly(N-isopropylacrylamide)-Clay Nanocomposites with Enhanced Temperature Response," in Langmuir, 2000, 16, 9895-9899) in view of Sablosky et al. (US 5,300,291) or Tezuka et al. (US 5,571,516).

Liang discloses nanocomposites of polymer-clay (title) and in one embodiment, the clay in the composite is at 20 wt% based on the dry weight of the composite (page 9897, 2nd full paragraph). The composite of Liang does not contain active compounds. The product containing the drug and the composite is the reservoir and meets the reservoir limitation of claim 5. But Liang suggests that the polymer, PNIPAAm, is known to be used in the delivery of drugs. Furthermore, Sablosky teaches that clay such as montmorillonite is a carrier for drugs (claim 11), Tezuka also teaches that montrillonite is a carrier for drugs (abstract and column 3, lines 18-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made use the composite of PNIPAAm and clay for drug delivery by incorporating the drug desired to be delivered/released.

Information Disclosure Statement

12. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Priority

Examiner acknowledges this application as claiming the benefits of provisional application 60/464,829 filed 04/23/03.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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